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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,214	02/22/2002	Roger D.A. Lipman	47915/KMO	1358

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EXAMINER	
GHALI, ISIS A D	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 12/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,214	LIPMAN, ROGER D.A.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/20/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's IDS, filed 01/20/2004; and request under 1.114, request for extension of time and declaration, all filed 09/07/2004.

Claims 1-5 and 7-16 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/07/2004 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-5 and 7-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,231,369 ('369) in view of US 5,817,332 ('332).

US '369 teaches an adhesive sealing material for use in connection to ostomy devices composed of continuous rubber phase and hydrocolloid dispersed in the continuous phase, i.e. forming discontinuous phase (abstract; col.4, lines 30-31, 55-60). The rubber phase is made of styrene copolymer and polyisobutylene wherein the styrene copolymer forms 40 wt % or below of the of the rubber (col.5, lines 8-10, 36-37, 46). Example O, Table III, shows that the styrene copolymer "Cariflex" forms 10.9% of the composition, and polyisobutylene forms 18.1 % of the composition. The hydrocolloid is a mixture of more than one hydrocolloid in an amount ranges from 48-56 % (col.8, lines 52-54). The composition further comprises oils, medicaments, or bactericides (col.6, lines 33, 45-47). The composition is supplied by release liner, i.e. substrate (col.9, lines 1-2).

The reference does not list cyclodextrin among the hydrocolloids, or the material of the backing.

The non-adhesive water proof backing are well known in the art, and are widely used for wound dressings and transdermal drug delivery devices.

US '332 teaches a transdermal device for the delivery of therapeutic agent comprises the drug complexed with cyclodextrin to enable steady state of drug release because cyclodextrin increase the water solubility of many drugs by complexing them into the hydrophobic cavity of the cyclodextrin (abstract; col.2, lines 52-56, 63-64; col.4, lines 37-39). The device comprises the cyclodextrin drug complex forming plurality of

cores dispersed in a polymer matrix and a backing layer (col.3, lines 50-53, 60; col.5, lines 21-30). The drug includes antibacterial agents (col.5, line 5).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a composition comprising continuous rubbery phase and discontinuous hydrocolloid phase as disclosed by US '369, and replace the hydrocolloid by cyclodextrin complexed with drugs as disclosed by US '332, motivated by the teaching of US '332 that drugs complexed with cyclodextrin enable steady state of drug release because cyclodextrin increase the water solubility of many drugs by complexing them into the hydrophobic cavity of the cyclodextrin, with reasonable expectation of having a composition comprising rubbery continuous phase and cyclodextrin discontinuous phase that release drug from the devices containing the composition at steady controlled rate with success.

4. Claims 1-5 and 7-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,367,732 ('732) in view of US '332.

US '732 teaches a skin barrier comprises an adhesive layer comprising discontinuous hydrocolloid phase dispersed in a continuous phase comprising styrene copolymers and polyisobutylene (abstract; col.5, lines 24-26, 49; col.6, lines 35-36; col.8, lines 31-42, 62-64). The adhesive composition further comprises bacteriostatic or fungicidal agents (col.6, line 59). The hydrocolloid phase comprises at least one hydrocolloid, and forms 10-55% of the composition of the adhesive layer (col.8, lines 53-55; col.9, lines 22-23). The styrene copolymer forms 10-40% of the continuous

phase (col.9, line 16). The skin barrier further comprises a non-adhesive, water impervious film secured to the adhesive layer (col.3, lines 54-56).

The reference does not list cyclodextrin among the hydrocolloids.

US '332 teaches a transdermal device for the delivery of therapeutic agent comprises the drug complexed with cyclodextrin to enable steady state of drug release because cyclodextrin increase the water solubility of many drugs by complexing them into the hydrophobic cavity of the cyclodextrin (abstract; col.2, lines 52-56, 63-64; col.4, lines 37-39). The device comprises the cyclodextrin drug complex forming plurality of cores dispersed in a polymer matrix and a backing layer (col.3, lines 50-53, 60; col.5, lines 21-30). The drug includes antibacterial agents (col.5, line 5).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a composition comprising continuous rubbery phase and discontinuous hydrocolloid phase as disclosed by US '732, and replace the hydrocolloid by cyclodextrin complexed with drugs as disclosed by US '332, motivated by the teaching of US '332 that drugs complexed with cyclodextrin enable steady state of drug release because cyclodextrin increase the water solubility of many drugs by complexing them into the hydrophobic cavity of the cyclodextrin, with reasonable expectation of having a composition comprising rubbery continuous phase and cyclodextrin discontinuous phase that release drug from the devices containing the composition at steady controlled rate with success.

5. Claims 1-5 and 7-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/14282 ('282) in view of US '332.

WO '282 teaches a pressure sensitive adhesive material comprising continuous phase of rubber comprising styrene copolymer and polyisobutylene; and a discontinuous phase comprising hydrocolloid (abstract). The discontinuous phase forms 15-70 wt % of the composition (page 11, first paragraph). The styrene copolymer forms 10-30 wt % of the composition, and the polyisobutylene forms 20-60 wt % of the composition (page 15, claims 1-4). Example 2, page 13, shows that the composition comprising more than one hydrocolloid. The composition comprises bactericides (page 11, third paragraph). The adhesive composition is coated on non-adhesive waterproof film and used in adhesive barrier or dressing for medical use (page 16, claim 13).

The reference does not list cyclodextrin among the hydrocolloids.

US '332 teaches a transdermal device for the delivery of therapeutic agent comprises the drug complexed with cyclodextrin to enable steady state of drug release because cyclodextrin increase the water solubility of many drugs by complexing them into the hydrophobic cavity of the cyclodextrin (abstract; col.2, lines 52-56, 63-64; col.4, lines 37-39). The device comprises the cyclodextrin drug complex forming plurality of cores dispersed in a polymer matrix and a backing layer (col.3, lines 50-53, 60; col.5, lines 21-30). The drug includes antibacterial agents (col.5, line 5).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a composition comprising continuous rubbery phase and discontinuous hydrocolloid phase as disclosed by WO '282, and replace the

hydrocolloid by cyclodextrin complexed with drugs as disclosed by US '332, motivated by the teaching of US '332 that drugs complexed with cyclodextrin enable steady state of drug release because cyclodextrin increase the water solubility of many drugs by complexing them into the hydrophobic cavity of the cyclodextrin, with reasonable expectation of having a composition comprising rubbery continuous phase and cyclodextrin discontinuous phase that release drug from the devices containing the composition at steady controlled rate with success.

Response to Arguments

6. Applicant's arguments filed 09/07/2004 have been fully considered but they are not persuasive. Applicant traverses the above rejections by arguing that US '369, US '732 and WO '282 do not teach cyclodextrin, and US '332 teaches cyclodextrin enable steady-state drug release. US '369 teaches the starch as not very suitable hydrocolloid for the discontinuous phase, and cyclodextrin is derived from starch. The combination of the references would not have resulted into the present invention. Without the benefit of the hindsight of the present invention, a skilled artisan would see no suggestion in the references for two hydrocolloids, one of which is cyclodextrin.

In response to the above argument, the examiner position is that the claims are directed to composition, and all the elements of the composition are taught by the combined teaching of the reference. The intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order

to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Further, one cannot show nonobviousness by attacking the references individually where the rejections are based on combination of references. *See In re Keller*, 208 USPQ 871 (CCPA 1981*); In re Merck & Co.*, 231 USPQ 375 (Fed. Cir. 1986). All the primary references teach the combination of hydrocolloids, and the secondary reference teaches cyclodextrin for transdermal application, thus, the combination is reasonable. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972). The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

The disclosed examples and preferred embodiment do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, on having ordinary skill in the art would have been motivated by the teaching of US '332 that drugs complexed with cyclodextrin enable steady state of drug release because cyclodextrin increase the water solubility of many drugs by complexing them into the hydrophobic cavity of the cyclodextrin, with reasonable expectation of having a composition comprising rubbery continuous phase and cyclodextrin discontinuous phase that release drug from the devices containing the composition at steady controlled rate with success. Applicant also desired drug delivery at the site of application of the adhesive.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does

not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Response to Amendment

7. The declaration under 37 CFR 1.132 filed 09/07/2004 is insufficient to overcome the rejection of claims 1-5 and 7-16 based upon obvious as set forth in the last Office action because: it refer(s) only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims that are directed to composition, and not method of it use as odor absorbent. See MPEP § 716. It include(s) statements which amount to an affirmation that the claimed subject matter functions as it was intended to function as odor absorbent. This is not relevant to the issue of nonobviousness of the claimed subject matter and provides no objective evidence thereof. See MPEP § 716.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

Isis Ghali